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510(k) Summary

AUG 24 2012

Owner's Name & Address:

LDR Spine USA
13785 Research Blvd. Suite 200
Austin, TX 78750

Contact Person:

Bradley W. Strasser
Regulatory Affairs Project Manager
Phone: (512) 344-3395
Fax: (512) 795-8306
Email: bradstrasser@ldrspine.com

Date:

August 06, 2012

Trade Name:

LDR Spine USA EasySpine® Posterior Spinal System
LDR Spine USA MC+™ Implant System
LDR Spine USA ROI® Implant System
LDR Spine USA ROI-A® Implant System
LDR Spine USA ROI-C® Implant System
LDR Spine USA ROI-T® Implant System

Common Name:

Spinal Pedicle Screws
Intervertebral Body Fusion Device
Spinal Vertebral Body Replacement Device

Classification:

NKB (21 CFR 888.3070) - Pedicle Screw Spinal System

MAX (21 CFR 888.3080) - Intervertebral Fusion Device with Bone Graft, Lumbar

MNH (21 CFR 888.3070) - Orthosis, Spondylolisthesis Spinal Fixation

MNI (21 CFR 888.3070) - Orthosis, Spinal Pedicle Fixation

KWP (21 CFR 888.3050) - Orthosis, Spinal Interlaminal Fixation

MQP (21 CFR 888.3060) - Spinal Vertebral Body Replacement Device

OVD (21 CFR 888.3080) - Intervertebral Fusion Device with Integrated Fixation, Lumbar

ODP (21 CFR 888.3080) - Intervertebral Fusion Device with Bone Graft, Cervical

OVE (21 CFR 888.3080) - Intervertebral Fusion Device with Integrated Fixation, Cervical

Predicate Devices:

Easyspine® Posterior Spinal System K043094, K063794, K070341, K082592

ROI® Implant System K043349

MC+™ Implant System K091088

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ROI-A® Implant System K082262, K090507

ROI-C® Implant System K091088

ROI-T® Implant System K082262

Device Description:

The LDR Spine implant systems identified above are medical devices designed to stabilize and promote fusion in the cervical and thoracolumbar spine. The materials used in their manufacture are titanium alloy (ASTM F136), tantalum (ASTM F560), and PEEK OPTIMA® LT1

The purpose of this 510(k) submission is solely to add MR Conditional labeling to LDR Spine's vertebral body replacement and interbody fusion cage systems (*ROI*, *MC+*, *ROI-A*, *ROI-C*, *ROI-T*), and to update the steam sterilization recommendations for all non-sterile instruments, cases, and trays for the above listed vertebral body replacement and intervertebral body fusion cages, as well as the Easyspine pedicle screw system.

The subject device systems remain unchanged relative to their predicates with respect to indications for use, material, design and performance characteristics.

Indications for Use:

The indications for use for systems discussed in this submission are identical to those cleared previously in predicate premarket notifications.

Non-Clinical Performance Data:

MR compatibility testing was completed using methods described in the following ASTM standards:

- ASTM F2052-06
- ASTM F2213-06
- ASTM F2119-07
- ASTM F2182-09

Non-clinical performance testing for MR compatibility was conducted on the *ROI*, *MC+*, *ROI-A*, *ROI-C*, and *ROI-T* vertebral body replacement and intervertebral body fusion implants and included:

- Magnetically-induced angular displacement
- Magnetically-induced torque
- MR imaging artifact analysis
- Differential heating in the MR environment

Test results indicate that the PEEK interbody fusion cages and anchor plates (where applicable) and vertebral body replacement devices meet the ASTM recommendations for MR-Conditional labeling in terms of device heating, magnetically induced displacement, and MRI artifacts.

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A Steam Sterilization validation for the LDR Spine non-sterile devices associated with the Easyspine pedicle screw system and the *ROI*, *MC+*, *ROI-A*, *ROI-C*, and *ROI-T* vertebral body replacement and intervertebral body fusion implants was also performed in accordance with the following standards:

- AAMI TIR12
- ANSI AAMI ST79
- ISO 17655-1
- AAMI TIR 39

Testing consisted of steam sterilization testing which confirmed that the non-sterile devices achieved a SAL of 10^{-6} when exposed to a steam sterilization cycle meeting the recommended cycle parameters outlined in AAMI ANSI ST79.

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LDR Spine USA, Incorporated
% Mr. Bradley Strasser
Regulatory Affairs Project Manager
13785 Research Boulevard, Suite 200
Austin, Texas 78750

AUG 24 2012

Re: K121103
Trade Name: LDR Spine USA EasySpine® Posterior Spinal System,
LDR Spine USA MC+™ Implant System,
LDR Spine USA ROI® Implant system,
LDR Spine USA ROI-A® Implant system,
LDR Spine USA ROI-C® Implant system,
LDR Spine USA ROI-T® Implant system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP, MAX, ODP, OVD, OVE, MQP
Dated: July 24, 2012
Received: July 25, 2012

Dear Mr. Strasser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

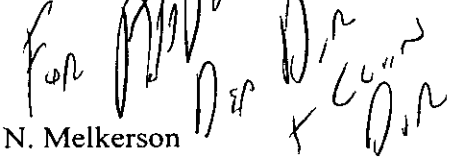
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121103

Device Name: LDR Spine USA EasySpine® Posterior Spinal System

Indications for Use:

The *Easyspine*® Posterior Spinal System is a posterior, non-cervical pedicle and non-pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121103

INDICATIONS FOR USE

510(k) Number (if known): K121103

Device Name: LDR Spine USA MC+™ Implant System

Indications for Use:

When used as an intervertebral body fusion device, the *MC+* Implant System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of nonoperative treatment prior to treatment with the device. The *MC+* Implant System is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation is required to properly utilize this system.

When used as a vertebral body replacement device, the *MC+* Implant System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system. These devices are intended to be used with autograft or allograft bone.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121103

INDICATIONS FOR USE

510(k) Number (if known): K121103

Device Name: LDR Spine USA ROI® Implant System

Indications for Use:

The *ROI* Partial Vertebral Body Replacement System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. *ROI* Partial Vertebral Body Replacement implants may be implanted singularly or in pairs. Supplemental internal fixation is required to properly utilize the system.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K121103

INDICATIONS FOR USE

510(k) Number (if known): K121103

Device Name: LDR Spine USA ROI-A® Implant System

Indications for Use:

When used as an intervertebral body fusion device, the *ROI-A* Implant System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121103

INDICATIONS FOR USE

510(k) Number (if known): K121103

Device Name: LDR Spine USA ROI-C® Implant System

Indications for Use:

The *ROI-C* Implant System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The LDR Spine *ROI-C* Implant System is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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and Restorative Devices

510(k) Number K121103

INDICATIONS FOR USE

510(k) Number (if known): K121103

Device Name: LDR Spine USA ROI-T® Implant System

Indications for Use:

When used as an intervertebral body fusion device, the *ROI-T* Implant System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

When used as a vertebral body replacement device, the *ROI-T* Implant System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. Supplemental internal fixation is required to properly utilize the system. These devices are intended to be used with autograft or allograft bone.

The *ROI-T* implants may be implanted singularly or in pairs.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K121103